

FORM PTO-1390
(REV. 11-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

HBC 232-KFM

U.S. APPLICATION NO. (If known, see 37 CFR 1.5

09/936571

INTERNATIONAL APPLICATION NO.

PCT/DE00/00334

INTERNATIONAL FILING DATE

3/FEBRUARY/00 ✓

PRIORITY DATE CLAIMED

4/FEBRUARY/99 ✓

TITLE OF INVENTION

DEVICE FOR RECEIVING AND CONTROLLING VOIDED URINE

APPLICANT(S) FOR DO/EO/US

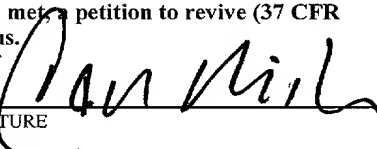
RAHE, MARTIN ✓

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:
PRELIMINARY EXAMINATION REPORT (in German)

09/936571 INTERNATIONAL APPLICATION NO PCT/DE00/00334		ATTORNEY'S DOCKET NUMBER HBC 232-KFM	
21. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$1000.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$860.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$710.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$690.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 ENTER APPROPRIATE BASIC FEE AMOUNT =		CALCULATIONS PTO USE ONLY <div style="border: 1px solid black; padding: 5px; margin: 5px;"> 860.00 </div>	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	14 - 20 =		x \$18.00
Independent claims	1 - 3 =		x \$80.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$270.00
TOTAL OF ABOVE CALCULATIONS =		\$	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.		+ \$ 430.00	
SUBTOTAL =		\$ 430.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).		\$	
TOTAL NATIONAL FEE =		\$ 430.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +		\$	
TOTAL FEES ENCLOSED =		\$ 430.00	
		Amount to be refunded:	\$
		charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>430.00</u> to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-0427</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.			
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted before the application can proceed to pending status.			
SEND ALL CORRESPONDENCE TO: MILDE, HOFFBERG & MACKLIN, LLP 10 BANK STREET SUITE 460 WHITE PLAINS, NEW YORK 10606			
Date of Deposit <u>9-14-01</u> I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.		SIGNATURE  <u>Karl F. Milde, Jr.</u> 24,822 REGISTRATION NUMBER	

HBC 232-KFM
15751 PCT/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : MARTIN RAHE
Serial No. : TO BE ASSIGNED
Filed : HEREWITH
For : DEVICE FOR RECEIVING AND CONTROLLING
VOIDED URINE

September 14, 2001

Hon. Commissioner of Patents
& Trademarks
Washington, DC 20231

Sir:

PRELIMINARY AMENDMENT

Prior to examination, please amend the above-identified
patent application as follows:

IN THE SPECIFICATION:

On page 1, after the title, insert the following
heading:

BACKGROUND OF THE INVENTION

and change the first paragraph to read as follows:

This invention concerns a device for receiving and examining
voided urine and, in particular, urine uncontrollably
voided.

09/936571-0001

On page 3, change the last paragraph to read as follows:

A measuring cell is also known from the International Patent Publication No. WO 92/15863 A, which features one inflow opening and one indicator on an indicator holder. The measuring cell is provided with one opening which creates a sort of viewing window, so that the indicators can be seen. These indicators are connected to a side of the indicator holder that borders the viewing window. Additionally, a liquid transport means, suitable for the transport of liquids due to its capillary, stretches from the inflow opening to the indicator holder. This liquid transporting means is, in this case, a foil layer connected with an area of each indicator.

Also in this measuring cell, the color transfer of the indicators is difficult to detect, thus making a reliable interpretation impossible.

SUMMARY OF THE INVENTION

The object of this invention is to improve a known device so that the detection of the color transfer in the indicators

and the reliability of the resulting interpretation can be improved in order to allow a clear and reliable determination of the urines composition. Moreover, it must be possible to adjust the device to different fields of application.

On page 4, change the first paragraph to read as follows:

This object, as well as other objects which will become apparent in the discussion that follows are achieved, in accordance with the present invention, by providing a device of the type described above having at least one viewing window to which the indicators can be seen, wherein the indicators are arranged on a side bordering the viewing window of an indicator holder, and wherein a liquid transporting means suitable for the transport of liquids due to its capillary action, wraps the indicator holder at the end of the inflow opening and is connected with at least one area of one indicator on one side bordering the viewing window.

On page 6, delete the last paragraph and substitute the following heading and paragraph:

For a full understanding of the present invention, reference should now be made to the following detailed description of the preferred embodiments of the invention as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

On page 7, after line 6, insert the following heading and paragraph:

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The preferred embodiments of the present invention will now be described with reference to Figures 1-3 of the drawings. Identical elements in the various figures are designated with the same reference numerals.

On page 10, after the last line, insert the following paragraphs:

In all the implementation forms the capillary pressure generated by the foil paper should be sufficiently high to fill the measuring cell completely with urine and remove the

air present in the measuring cell at the beginning of the measurement.

There has thus been shown and described a novel device for receiving and controlling voided urine which fulfills all the objects and advantages sought therefor. Many changes, modifications, variations and other uses and applications of the subject invention will, however, become apparent to those skilled in the art after considering this specification and the accompanying drawings which disclose the preferred embodiments thereof. All such changes, modifications, variations and other uses and applications which do not depart from the spirit and scope of the invention are deemed to be covered by the invention, which is to be limited only by the claims which follow.

IN THE CLAIMS:

In line 1, delete "Patent Claims" and insert:

C L A I M S

What is claimed is:

Please amend claims 1-13 to read as follows:

1. In a device for the absorption and the examination of voided urine, in the form of a measuring cell, which

comprises at least one inflow opening, a plurality of indicators and at least one viewing window creating a transparent area, through which the indicators can be seen, the improvement wherein the indicators are arranged on a side bordering the viewing window of an indicator holder, and wherein a liquid transporting means, suitable for the transport of liquids due to its capillary action, wraps the indicator holder at the end of the inflow opening and is connected with at least one area of one indicator on the side bordering the viewing window.

2. Device according to claim 1, wherein a swelling material is placed between the indicator holder and the inflow opening.

3. Device according to claim 2, wherein the swelling material is a swelling cushion made of swelling foil.

4. Device according to claim 3, wherein the swelling cushion is lined with a film and the film is provided with an inflow opening, and wherein the inflow openings, the measuring cell and the swelling cushion are placed directly one behind the other.

5. Device according to claim 1, wherein the liquid transporting means reaches the area of the inflow opening.

6. Device according to claim 1, wherein the liquid transporting means wraps around the back side of the indicator holder.

7. Device according to claim 1, wherein the liquid transporting means is part of the swelling material.

8. Device according to claim 1, wherein the liquid transporting means is foil paper.

9. Device according to claim 1, wherein the liquid transporting means is a material made of non cellulose material.

10. Device according to claim 1, wherein the liquid transporting means is impregnated with indoxylester to improve the detection of the leukocyte quantity pro volume, such that due to the higher concentration of indoxylester,

more indoxyl is released with a consequent darker and qualitatively more meaningful coloration of the indicators.

11. Device according to claim 1, wherein the liquid transporting means is prepared with substances which positively affect the reaction process of the indicators with regard to color stabilization, sensitivity, and the foil's features.

12. Device according to claim 1, further comprising conveying bands of different width arranged on the liquid transporting means to control the quantity of the urine in such a way that the various indicators can receive a quantity of test liquid necessary to ensure perfect functionality.

13. Device according to claim 1, wherein the measuring cell is made of PP-foil.

Please add the following new claim:

14. Device according to claim 1, wherein, the liquid transporting means develop a capillary pressure sufficient to fill the measuring cell with liquid.

IN THE ABSTRACT:

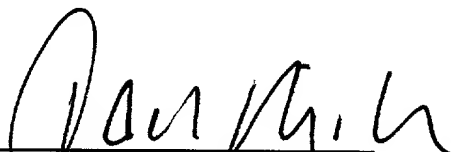
Please add the following ABSTRACT OF THE DISCLOSURE on the attached sheet.

R E M A R K S

This Preliminary Amendment is being filed to place the specification and claims in proper form under United States Patent Practice also to add an Abstract. No new matter has been introduced.

Respectfully submitted,

By



Karl F. Milde, Jr.

Reg. No. 24,822

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ABSTRACT OF THE DISCLOSURE

Indicators (4) are provided on one side of an indicator carrier (5) for controlling urine which has been caught in a measuring cell (1). The indicators can be perceived through a window (3). The measuring cell (1) is provided with an inlet on the side opposite the window (3). The aim of the invention is to guide urine from the inlet (6) to the indicators (4). To this end, the inventive device has a fluid transport means (9), e.g., blotting paper, which can transport fluid by virtue of the capillarity thereof. A soaking material, e.g., a soaking cushion, can be arranged between the inlet (6) and the indicator carrier (5). Said cushion becomes soaked and locks the inlet (6) when catching urine.

1/pat.

VERSION TO SHOW MARKINGS OF CHANGES MADE

IN THE SPECIFICATION:

On page 1, after the title, insert the following heading:

BACKGROUND OF THE INVENTION

and lines 4 and 5, delete ", according to the general concept of patent claim 1".

On page 3, delete lines 15-19 and insert -- A measuring cell is also known from the International Patent Publication No. WO 92/15863 A, which features one inflow opening and one indicator on an indicator holder. The measuring cell is provided with one opening which creates a sort of viewing window, so that the indicators can be seen. These indicators are connected to a side of the indicator holder that borders the viewing window. Additionally, a liquid transport means, suitable for the transport of liquids due to its capillary, stretches from the inflow opening to the indicator holder. This liquid transporting means is, in this case, a foil layer connected with an area of each indicator.

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Also in this measuring cell, the color transfer of the indicators is difficult to detect, thus making a reliable interpretation impossible.

SUMMARY OF THE INVENTION

The object of this invention is to improve a known device so that the detection of the color transfer in the indicators and the reliability of the resulting interpretation can be improved in order to allow a clear and reliable determination of the urines composition. Moreover, it must be possible to adjust the device to different fields of application. --

On page 4, delete lines 1-3 and insert -- This object, as well as other objects which will become apparent in the discussion that follows are achieved, in accordance with the present invention, by providing a device of the type described above having at least one viewing window to which the indicators can be seen, wherein the indicators are arranged on a side bordering the viewing window of an indicator holder, and wherein a liquid transporting means suitable for the transport of liquids due to its capillary action, wraps the indicator holder at the end of the inflow

opening and is connected with at least one area of one indicator on one side bordering the viewing window. --

On page 6, delete lines 18 and 19, and insert the following heading and paragraph:

-- For a full understanding of the present invention, reference should now be made to the following detailed description of the preferred embodiments of the invention as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS --

On page 7, after line 6, insert the following heading and paragraph:

-- DESCRIPTION OF THE PREFERRED EMBODIMENTS

The preferred embodiments of the present invention will now be described with reference to Figures 1-3 of the drawings. Identical elements in the various figures are designated with the same reference numerals. --

On page 10, after the last line, insert the following paragraphs:

-- In all the implementation forms the capillary pressure generated by the foil paper should be sufficiently high to fill the measuring cell completely with urine and remove the air present in the measuring cell at the beginning of the measurement.

There has thus been shown and described a novel device for receiving and controlling voided urine which fulfills all the objects and advantages sought therefor. Many changes, modifications, variations and other uses and applications of the subject invention will, however, become apparent to those skilled in the art after considering this specification and the accompanying drawings which disclose the preferred embodiments thereof. All such changes, modifications, variations and other uses and applications which do not depart from the spirit and scope of the invention are deemed to be covered by the invention, which is to be limited only by the claims which follow. --

IN THE CLAIMS:

In line 1, delete "Patent Claims" and insert:

C L A I M S

What is claimed is:

Please amend claims 1-13 to read as follows:

1. (Once Amended) [Device] In a device for the absorption and the examination of voided urine, in the form of a measuring cell [(1)], which [includes] comprises at least one inflow opening, [(6) and] a plurality of indicators [(4) inside of it, and the measuring cell (1) must include] and at least one viewing window [(3)] creating a transparent area, through which the indicators [(4)] can be seen, [characterized in that] the improvement wherein the indicators [(4)] are arranged on a side bordering [with] the viewing window [(3)] of an indicator holder [(5)], and [that] wherein a liquid transporting means [(9)], suitable for the transport of liquids due to its capillary action, wraps the indicator holder [(5)] at the end of the inflow opening [(6)] and is connected with at least one area of one indicator [(4)] on the side bordering [with] the viewing window.

2. (Once Amended) Device according to claim 1, [characterized in that] wherein a swelling material is placed between the indicator holder [(5)] and the inflow opening [(6)].

3. (Once Amended) Device according to claim 2, [characterized in that] wherein the swelling material is a swelling cushion [(7)] made of swelling foil.

4. (Once Amended) Device according to claim 3, [characterized in that] wherein the swelling cushion [(7)] is lined with a film [(7a)] and the film is provided with an inflow opening, [(8)], in which] and wherein the inflow openings [(6, 8)], the measuring cell [(1)] and the swelling cushion [(7)] are placed directly one behind the other.

5. (Once Amended) Device according to [one of the previous claims, characterized in that,] claim 1, wherein the liquid transporting means [(9)] reaches the area of the inflow opening [(6)].

6. (Once Amended) Device according to [one of the previous claims, characterized in that,] claim 1, wherein the liquid transporting means [(9)] wraps around the back side of the indicator holder [(5)].

7. (Once Amended) Device according to [one of the previous claims, characterized in that,] claim 1, wherein the liquid transporting means [(9)] is part of the swelling material.

8. (Once Amended) Device according to claim [6, characterized in that,] 1, wherein the liquid transporting means [(9)] is foil paper.

9. (Once Amended) Device according to [one of the claims from 1 to 5, characterized in that,] claim 1, wherein the liquid transporting means [(9)] is a material made of non cellulose material.

10. (Once Amended) Device according to [one of the previous claims, characterized in that, in order to improve the detection of the leukocyte quantity pro volume,] claim 1, wherein the liquid transporting means [(9)] is impregnated with indoxylester[, so] to improve the detection of the leukocyte quantity pro volume, such that due to the higher concentration of indoxylester, [causes] more indoxyl is released with a consequent darker and qualitatively more meaningful coloration of the indicators [(4)].

11. (Once Amended) Device according to [one of the previous claims, characterized in that,] claim 1, wherein the liquid transporting means [(9)] is prepared with substances which [can] positively affect the reaction process of the indicators [(4)]

with regard to color stabilization, sensitivity, and the foil's features.

12. (Once Amended) Device according to [one of the previous claims, characterized in that,] claim 1, further comprising conveying bands [(10)] of different width [are] arranged on the liquid transporting means [(9) in order] to control the quantity of the urine in such a way that the various indicators [(4)] can receive a quantity of test liquid necessary to ensure perfect functionality.

13. (Once Amended) Device according to [one of the previous claims, characterized in that,] claim 1, wherein the measuring cell is made of PP-foil.

Please add the following new claim:

-- 14. Device according to claim 1, wherein, the liquid transporting means develop a capillary pressure sufficient to fill the measuring cell with liquid. --

IN THE ABSTRACT:

Please add the following ABSTRACT OF THE DISCLOSURE on the attached sheet.

ABSTRACT OF THE DISCLOSURE

Indicators (4) are provided on one side of an indicator carrier (5) for controlling urine which has been caught in a measuring cell (1). The indicators can be perceived through a window (3). The measuring cell (1) is provided with an inlet on the side opposite the window (3). The aim of the invention is to guide urine from the inlet (6) to the indicators (4). To this end, the inventive device has a fluid transport means (9), e.g., blotting paper, which can transport fluid by virtue of the capillarity thereof. A soaking material, e.g., a soaking cushion, can be arranged between the inlet (6) and the indicator carrier (5). Said cushion becomes soaked and locks the inlet (6) when catching urine.

DEVICE FOR RECEIVING AND CONTROLLING VOIDED URINE

This invention concerns a device for receiving and examining voided urine and, in particular, urine uncontrollably voided, according to the general concept of patent claim 1.

A device of this type is already known from the European Patent No. EP 0 560 099 A2. This refers to a coating which wraps and, sometimes, defines the inner space of the device. This coating has at least one passage to let the liquid being examined, urine, flow into the inner part of the device for a pre-determined period of time. Moreover, a device to absorb the liquid, urine, into the inner part of the device as well as a means to stop the flow of the liquid is provided. The composition of the liquid to be examined is determined by means of suitable indicating cards (check-up cards). Because of the limited construction of these cards, their use implies a disadvantage as far as the related reading of the results is concerned, seeing that they cannot be seen from the side of the device bordering with the liquid to be examined.

The European Patent No. EP 0 438 482 B1 also describes a similar device for the absorption and examination of, in this case, uncontrollably voided urine; the device consists of a small

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measuring cell in the form of an "examination card", which is placed inside a transparent collecting bag, into which the urine flows by means of an inlet tube. The examination card is provided with indicators, to which urine is exposed, to examine the urine collected in terms of developing and existing pathogen infections, which, for example, correspond to the pH, nitrite, leukocyte and electrolyte values in the urine. The examination card is covered by a membrane, on the side exposed to the urine, which slows down the urines absorption, causing the urine to penetrate the indicators in a slower manner thus preventing incorrect measurements by reading the high pathogenic concentrations of the urine initially absorbed between the membrane and the indicators. Another swelling material is located which swells after the urine flows into the measuring cell and, by pushing against the membrane, causes the membrane to close after a set period of time. This action counteracts the flushing out of the indicating substances.

In this known measuring cell, the indicators can be observed by means of a transparent external film, acting as a viewing window on the side lying opposite the membrane, because, on the other side, the indicators are covered by the swelling material. This material must lie directly at the rear side of the indicators, so that these can be slowly soaked with urine from the back

until a color transfer takes place, which can be seen from the viewing window.

Very good indicators for this known device are available commercially which, due to manufacturing and technical reasons and because of their otherwise different use (as for example direct moisturising with urine to identify disease) are used on synthetic strips that are at least lightly opaque and almost white. When these indicators are used in the known device, they must be placed with their upper surface lying against the swelling material, so that the color transfer can be detected by means of the synthetic strips. However, given the minimal transparency of the material of which the strips are made, the color transfer can not be clearly determined and, in particular, the intensity of the color transfer is difficult to perceive.

The object of this invention is to improve a known device so as to make the indicators easy to read and to allow a clear and reliable determination of the urines composition. Moreover, it must be possible to adjust the device to different fields of application.

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This task is achieved by the invention through the characteristic features of patent claim 1. Further embodiments of the invention are described in the sub-claims.

Thus, this invention proposes the use of standard indicators arranged on a non-transparent holder and which can be seen through a viewing window in the measuring cell. In order to get the urine from the inflow opening, located on the side opposite the measuring cell, into the indicators, a liquid transporting means is used - foil paper - which, thanks to its capillaries, is suitable for the transport of liquids.

As in the known measuring cell, a swelling material can also be used in this case - a swelling fleece -, which is arranged between the indicator holder and the inflow opening and which swells as a result of the urines absorption and which closes the inflow opening of the measuring cell after a few minutes.

Within the framework of another variation of the device according to the invention, which is used especially in incontinence absorbing means (diapers), a separate swelling cushion is not used and the indicator holder is wrapped with foil paper or a similar capillary material. Here the seal of the system is of secondary importance. In this case, the foil paper

first allows the penetration of the liquid into the measuring cell and then, because of the small inflow openings used, the air pressure inside the measuring cell prevents the liquid from penetrating.

The quantity of leukocytes pro volume is determined as follows: The indicators contain indoxylester, which is cleft by means of granulocyte-esterase. It is subsequently possible to determine the quantity of leukocytes pro volume through the granulocyte-esterase concentration. The split product released, indoxyl, reacts with the diosonium salt in the indicators by producing a purple pigment. The color transfer can range between beige and purple, depending on the concentration.

In order to improve the detection of the leukocyte quantity, especially in case of a very small leukocyte concentration, within the framework of the invention, it is proposed to impregnate the used foil paper with indoxylester, in addition to the indicators. In this way more indoxyl is released and a darker hue is obtained due to the higher concentration of indoxylester because of the granulocyte-esterase. A darker color transfer is qualitatively more meaningful and much more stable than a lighter one because the detection is qualitatively improved.

In order to improve the reliability of the system even more, it is also proposed to adopt a more permeable foil paper to prevent the foil paper from retaining the relatively high quantity of leukocytes. The foil paper can be made more permeable by giving it grooves.

It is also proposed to prepare the foil paper with substances which can positively affect the reaction process of the indicators regarding color stabilization, sensitivity, and the foil's features. This prevents changes to the indicators contained in the measuring cell, after a long time (15-20 minutes). In this context, an indicator strip can be replaced with a specifically prepared paper or an additional soaked paper can be integrated into the test strips.

In order to function better, the different indicators need high quantities of test liquid. It is, therefore, proposed to design the conveying band for the test liquid with various widths, in order to control the quantity of the test liquid.

The invention is explained below in more detail on the basis of the drawing:

Figure 1 is a schematic side view of a first embodiment of the device according to the invention.

Figure 2 is a schematic side view of a second embodiment of the device according to the invention.

Figure 3 is a depiction of the foil paper back side according to a preferred embodiment of the invention.

In Figure 1, the device for the absorption and the examination of uncontrollably voided urine includes a closed and flat measuring cell 1 preferably made of PP-foil with a rear supporting foil 2 and a front see-through foil creating a transparent area, which works as a viewing window 3. Behind the viewing window 3, the indicators 4 are arranged on an indicator holder 5. One single 1 millimetre wide inflow opening 6 is located on the back support foil.

Moreover, the swelling material in the measuring cell 1 is preferably fitted with a swelling cushion 7, which is lined with a foil 7 and fitted with one single 1 millimetre wide inflow opening 8. The inflow openings 6 and 8 are located one directly behind the other.

A liquid transporting means 9, which in this implementation is a foil paper sheet suitable for the transport of liquids due to its capillary, surrounds the swelling cushion, the indicator holder and the indicators, in which one edge of the foil paper lies next to the inflow openings 6, 8 and the other edge covers an edge area of all the indicators.

The device works as follows: through the inflow openings 6, 8, the urine reaches the swelling cushion 7, swelling foil, which swells as a result. In the middle of the capillary foil paper used as a liquid transporting means 9, a small amount of urine is simultaneously absorbed which is transported round the swelling cushion 7 and the transparent indicator holder 5 to the indicators 4. The volume of the swelling cushion 7 increases with the swelling process and, as a result, the measuring cell closes after a few minutes. The capillary foil paper used as a liquid transporting means 9 can obviously be replaced by another means, for example a wick or a suitable liquid transport means not made of cellulose material.

Figure 2 shows another variation of the invention, which should be used especially with absorbing incontinence means (diapers). In this case, unlike the implementation described at the beginning, no separate swelling cushion is used, seeing that the

sealing of the system, in this case, is of secondary importance. The foil paper stretches over another area and wraps the whole rear side of the indicator holder 5. This implementation has a very short reaction time and the indicators need only a small quantity of urine. As a variation to this implementation example, a swelling cushion can also be used which runs round the indicator holder and is connected to an edge area of the indicator. In this way the swelling cushion and the liquid transport means are the same thing.

According to the invention, both implementations described can improve the detection of the leukocyte quantity, especially in case of a very small concentration of leukocytes, by using foil paper impregnated with indoxylester. As described at the beginning, the higher concentration of indoxylester causes more indoxyl to be released with a consequent darker and qualitatively more meaningful coloration.

The application of the principle that the foil paper should be prepared with substances which can positively affect the reaction process of the indicators with regard to color stabilization, sensitivity, the features of the foil, can be achieved within the framework of another variation of the invention.

According to Figure 3, the foil strips 10 of the test liquid have been designed with different widths in order to control the quantity of the test liquid, given that, to ensure better functionality, the various indicators need different quantities of test liquid. For example, the right foil band is wider than the other two in order to ensure a higher level of reliability and more transparency.

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Patent claims

1. Device for the absorption and the examination of voided urine, in the form of a measuring cell (1), which includes at least one inflow opening (6) and indicators (4) inside of it, and the measuring cell (1) must include at least one viewing window (3) creating a transparent area, through which the indicators (4) can be seen, characterized in that, the indicators (4) are arranged on a side bordering with the viewing window (3) of an indicator holder (5), and that a liquid transporting means (9), suitable for the transport of liquids due to its capillary, wraps the indicator holder (5) at the end of the inflow opening (6) and is connected with at least one area of one indicator (4) on the side bordering with the viewing window.

2. Device according to claim 1, characterized in that, a swelling material is placed between the indicator holder (5) and the inflow opening (6).

3. Device according to claim 2, characterized in that, the swelling material is a swelling cushion (7) made of swelling foil.

4. Device according to claim 3, characterized in that, the swelling cushion (7) is lined with a film (7a) and the film is

provided with an inflow opening (8), in which the inflow openings (6, 8), the measuring cell (1) and the swelling cushion (7) are placed directly one behind the other.

5. Device according to one of the previous claims, characterized in that, the liquid transporting means (9) reaches the area of the inflow opening (6).

6. Device according to one of the previous claims, characterized in that, the liquid transporting means (9) wraps around the back side of the indicator holder (5).

7. Device according to one of the previous claims, characterized in that, the liquid transporting means (9) is part of the swelling material.

8. Device according to claim 6, characterized in that, the liquid transporting means (9) is foil paper.

9. Device according to one of the claims from 1 to 5, characterized in that, the liquid transporting means (9) is a material made of non cellulose material.

10. Device according to one of the previous claims, characterized in that, in order to improve the detection of the

leukocyte quantity pro volume, the liquid transporting means (9) is impregnated with indoxylester, so that due to the higher concentration of indoxylester causes more indoxyl is released with a consequent darker and qualitatively more meaningful coloration of the indicators (4).

11. Device according to one of the previous claims, characterized in that, the liquid transporting means (9) is prepared with substances which can positively affect the reaction process of the indicators (4) with regard to color stabilization, sensitivity, and the foil's features.

12. Device according to one of the previous claims, characterized in that, conveying bands (10) of different width are arranged on the liquid transporting means (9) in order to control the quantity of the urine in such a way that the various indicators (4) can receive a quantity of test liquid necessary to ensure perfect functionality.

13. Device according to one of the previous claims, characterized in that, the measuring cell is made of PP-foil.

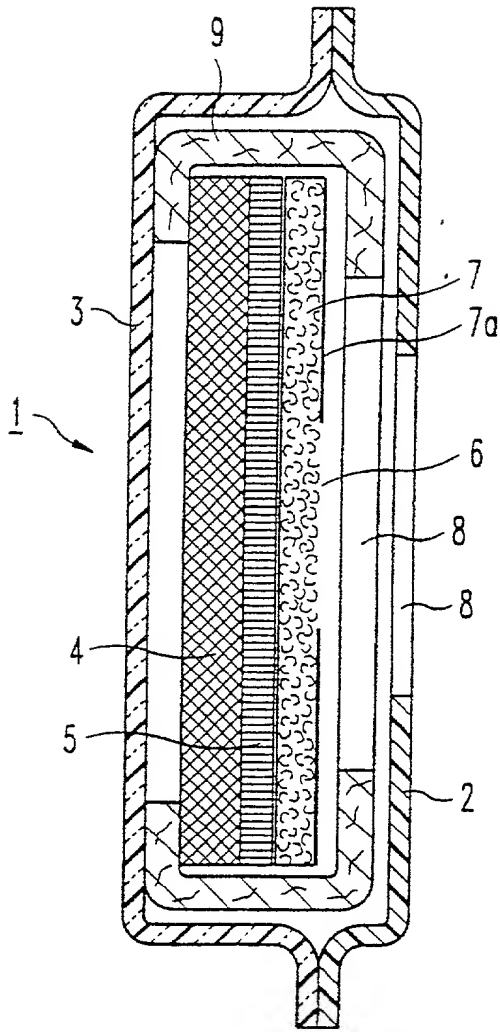


FIG. 1

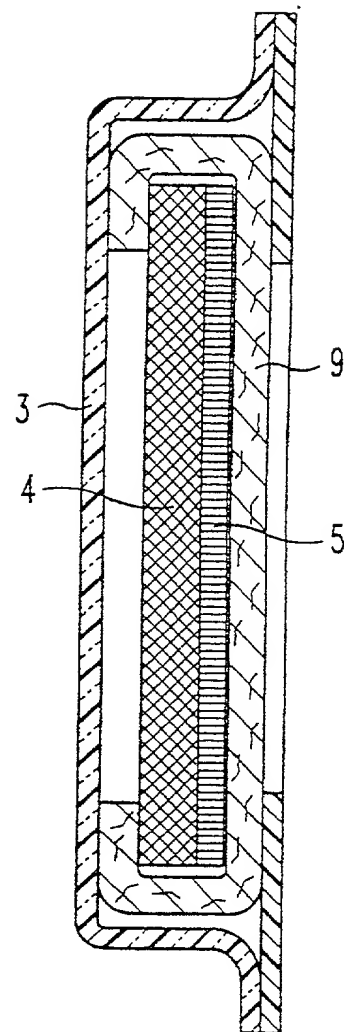


FIG. 2

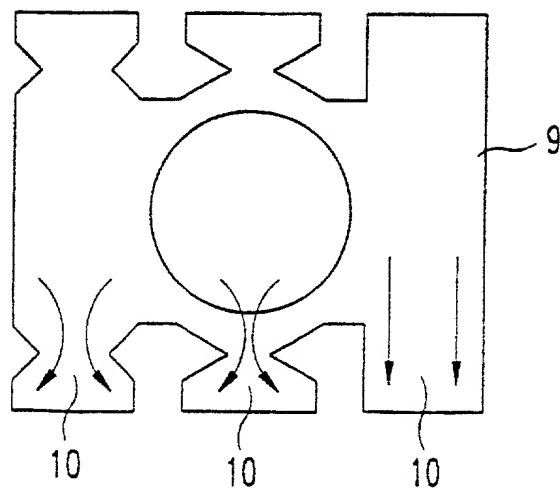


FIG. 3

FIG. 1

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**DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION**HBC 232-KFM

15751 US

As the below named inventors, I/We hereby declare that:

My/Our residence, post office address and citizenship is as stated below next to my/our name..

If one name appears below, I am the sole inventor of the subject matter sought to be patented.

If two or more names appear below, we are joint inventors of the subject matter sought to be patented

I/We believe I/We am/are the original; and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled

DEVICE FOR RECEIVING AND CONTROLLING VOIDED URINE

the specification of which

☒ is attached hereto.☐ was filed on _____ as application Serial No. _____

I/We hereby state that I/We reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I/We acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I/We also acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.63(d), which occurred between the filing date of the prior application and the filing date of the continuation-in-part application, if this is a continuation-in-part application.

I/We hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for the patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application: GERMAN Application No. 199 04 556.9
filed February 4, 1999✓Priority Claimed: X Yes No

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Prior Foreign Application: International Application No. PCT/DE00/00334
filed February 3, 2000

Priority Claimed: X Yes No

I/We hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.

Filing Date

Status
(patent, pending, abandoned)

I/We hereby declare that all statements made herein of my/our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I/We hereby appoint the following attorneys and/or agents to represent me with respect to the above identified U.S. Patent Application, and to prosecute any continuations, continuations-in-part, reissue applications and/or reexaminations with respect to these applications and to transact all business in the Patent and Trademark Office connected therewith, and hereby expressly revoke all prior powers, whatever they may be, heretofore had herein:

Karl F. Milde, Jr., Reg. No. 24, 822 and Steven M. Hoffberg, Reg. No. 33,511, both of 10 Bank Street, Suite 460, White Plains, New York 10606, my/our attorneys with full power of substitution and revocation.

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INVENTOR'S SIGNATURE

05.09.2001

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RESIDENCE

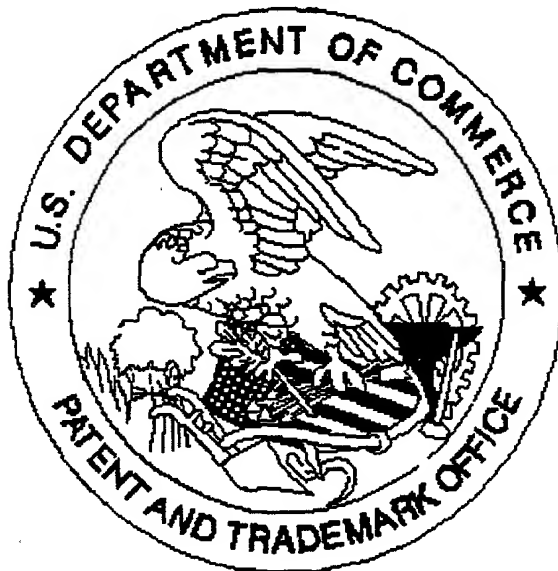
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